In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-551V

Filed: February 2, 2021

UNPUBLISHED

CLAIRE RUTZ, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Decision Dismissing Petition; Tdap Vaccine; Shoulder Injury; Biceps tendinitis

Bridget Candance McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On April 17, 2018, petitioner filed a claim under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that she suffered left shoulder injuries as a result of her receipt of the Tdap vaccination on November 12, 2016. (ECF No. 1.) On March 4, 2019, petitioner amended her petition to allege more specifically that she suffered bicep tendinitis as a result of her November 12, 2016 vaccination. (ECF No. 24.) On June 4, 2019, respondent filed his Rule 4 report, recommending against compensation. (ECF No. 27.) For the reasons discussed below, petitioner's case is DISMISSED.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

I. Procedural History

This case was originally assigned to the Special Processing Unit ("SPU") based on the allegations in the petition. (ECF No. 7.) Petitioner filed medical records and an affidavit along with her initial petition marked as Exhibits 1-6. (ECF No. 1.) From April to August of 2018, petitioner collected additional records marked as Exhibits 7-14. (ECF Nos. 11, 12, 14-17.) She filed a Statement of Completion on August 31, 2018. (ECF No. 18.) Thereafter, as noted above, she amended her petition on March 4, 2019. (ECF No. 24.) Additional records marked as Exhibits 15-16 were filed. (ECF No. 26, 28.) Respondent subsequently filed his Rule 4 report recommending against compensation on June 4, 2019. (ECF No. 27.) The case was briefly reassigned to another special master before ultimately being reassigned to me on August 29, 2019. (ECF No. 29-34.)

On November 18, 2019 I provided petitioner 60 days to file an expert report supporting her claim.[2] (ECF No. 35.) Following my initial scheduling order, I extended petitioner's expert report deadline on three separate occasions. On June 11, 2020, petitioner filed a status report indicating that she had been unable to secure an expert in this matter and requesting thirty days to inform the court on how she intended to proceed. (ECF No. 40.) Petitioner filed another status report on August 7, 2020 indicating that she intended to file a "letter of causation in support of her claim," by her treating orthopedist, Dr. Jess Alcid. (ECF No. 42.) Consequently, I extended petitioner's expert report deadline on two more occasions until October 26, 2020, ultimately providing petitioner to that time nearly one year to file her expert report.

On October 26, 2020, petitioner filed a status report indicating that she was still unable to retain an expert to support her claim and requesting a status conference to discuss the status of her case. (ECF No. 44.) During that status conference I advised that I would allow petitioner one final 90-day period to seek out an expert. I issued an Order to Show Cause on November 3, 2020 explaining at length why an expert report is necessary in this case. (ECF No. 45.) During the call, petitioner's counsel requested that petitioner herself be permitted to be heard in writing. (*Id.* at 5.) I explained that I would accept a written submission from petitioner pursuant to Vaccine Rule 8(d), but that such a submission would not be a substitute for an expert report. (*Id.*)

On January 29, 2021, petitioner filed her written memorandum. (ECF No. 46.) She did not, however, file any expert report. Her deadline to show cause why the case should not be dismissed lapsed on February 1, 2021, without the filing of any expert report. In her response to the Order to Show Cause, petitioner confirmed that she has been unsuccessful in securing an expert to opine in her case; however, she attributed that failure to the current Covid pandemic and significant shut-downs in her area. (ECF No. 46, p. 1.) She represented that she has been "cold-calling" rheumatologists, but that this has been fruitless. (*Id.*) She requested an indefinite extension of time until

[2] Petitioner's claim was prosecuted in tandem with a claim filed on her husband's behalf by the same counsel. During the period from August 2019, when the case was initially reassigned to me, until November 2019, when petitioner was first ordered to file an expert report, additional factual issues were being resolved in the other case relative to the vaccine administration record.

pandemic restrictions are lifted and she is able to safely pursue a physician's opinion in person, estimating that this would be six to nine months. (*Id.*) Petitioner described in some detail her reasons for receiving the Tdap vaccine and her regrets at having done so. She stressed that her primary care physician, Dr. Simone, and her rheumatologist, Dr. Dhar, agree that she experienced a vaccine reaction. (*Id.* pp. 1-2.) In conclusion, petitioner submits: "I ask you to review the copious previously submitted medical documentation regarding my claim. If you do not wish to provide an extension, then I ask you to consider the compelling evidence supporting my claim and award a positive judgement on my behalf." (*Id.* at 2.)

II. Factual History

Petitioner was a relatively healthy adult woman with no significant medical history before she received TDaP and Fluarix vaccinations on November 12, 2016. (Ex. 1, p. 7.) I have reviewed the entirety of the medical records filed in this case; however, the facts of petitioner's post-vaccination medical history are summarized only very briefly as follows.

Shortly after her vaccination, petitioner began to experience pain in her left arm. (ECF No. 1, p. 1.) Petitioner filed a VAERS report on January 29, 2017 reporting achiness in an undefined area that progressively spread to petitioner's bicep, elbow, and lower arm. (Ex. 2, p. 1.) Petitioner emailed GSK, the manufacturer of the vaccines at issue, on January 30, 2017. (Ex. 10.) Petitioner explained to GSK in this email that both she and her husband "had the Fluarix Quad and the Boostrix TDAP administered at a CVS on November 12, 2016," and that since receiving those vaccinations, "both [petitioner and her husband] are feeling weakness and pain in our bicep area, elbow, and lower arms." (*Id.*)

On February 27, 2017, petitioner presented to Simone Family Medicine seeking treatment for the pain in her left arm. (Ex. 8, p. 2) Petitioner's physical exam revealed full range of motion in her left arm, pain in her lateral epicondyle, and 5/5 grip strength. (*Id.*) Petitioner was diagnosed with lateral epicondylitis secondary to vaccination and prescribed physical therapy. (Ex. 3, p. 9.)

Petitioner began physical therapy at Kessler Rehabilitation Center ("Kessler") on March 15, 2017. (*Id.* at 26.) Petitioner's physical therapy records indicate an injury date of "11/22/16" and complaints of pain and weakness in her left arm which began after her November 12 vaccination. (*Id.*) The physical therapist noted that petitioner had slight pain in the hand, no numbness or tingling, and pain in the biceps aponeurosis, lateral epicondyle, and anterior forearm. (*Id.*) Petitioner was found to have normal left shoulder strength, left elbow and forearm strength of 2/5, left elbow flexion of 145 degrees, and normal range of motion in her wrist; no records indicate that petitioner's shoulder was evaluated. (*Id.* at 27.) Petitioner returned to Kessler for a physical therapy re-evaluation on April 19, 2017. (*Id.* at 30.) During this visit, petitioner's exam revealed improved elbow and forearm strength of 4/5. (Ex. 3, p. 31.) Notably, the records again do not indicate that petitioner's shoulder was evaluated. (*Id.*) Petitioner discontinued

her physical therapy on May 3, 2017, noting that she had improved, that she had lingering pain, and that she intended to seek a second opinion regarding her left arm issues. (Ex. 4, p. 2.)

Petitioner's left arm was re-examined at Simone Family Medicine on July 1, 2017. (Ex. 3, p. 10.) Following this exam, petitioner was diagnosed with persistent biceps tendinitis secondary to vaccination and referred to an orthopedist. (*Id.*)

Petitioner was examined at Ocean Orthopedic Associates by Dr. Jess Alcid. (Ex. 5, p. 71.) Following the exam, Dr. Alcid diagnosed petitioner with residual left elbow tendonitis "[p]ossibly from an inflammatory reaction from her vaccination." (Ex. 3, p. 36.) Petitioner received an MRI of her left elbow on August 10, 2017. (Ex. 5, p. 77.) Dr. Alcid reviewed petitioner's MRI, and diagnosed her with a left elbow biceps insertional tendonitis. (*Id.* at 80.) Dr. Alcid prescribed NSAIDS, icing, and home physical therapy. (*Id.*)

Petitioner did not seek any medical attention regarding her left elbow until August 9, 2018 when she was examined by Dr. Alcid for what was described as a "flare." (Ex. 14, p. 39.) Petitioner reported that her elbow had been improving but had felt persistently tender since she had injured her shoulder in an incident unrelated to her November 12, 2016 vaccination. (*Id.*) On exam petitioner was found to have tenderness of the distal biceps tendon and normal shoulder strength. (*Id.*) Petitioner did not seek any additional medical attention regarding her alleged vaccine injury after this final visit.

III. The Nature of Petitioner's Injury

To the extent petitioner initially pled that she suffered a shoulder injury, there is a concept known as a "Shoulder Injury Related to Vaccine Administration" or "SIRVA." As of March 21, 2017, SIRVA was added to the Vaccine Injury Table. 42 C.F.R. § 100.3(a). This means that if a shoulder injury meets the accompanying definition of SIRVA[3] and occurred within 48 hours of vaccination, the petitioner is entitled to a rebuttable presumption that the vaccine caused the injury.

Upon my review of her complete medical records, however, it appears that petitioner in this case did not suffer any vaccine-related shoulder injury at all, but instead appears to have suffered an injury to her elbow. Although petitioner specifically included an allegation in her amended petition that she suffered bicep tendinitis, this is a condition that can occur either at the level of the shoulder or at the level of the elbow. In her medical records, petitioner's physicians reference the distal bicep tendon and the

[3] In order to prove a SIRVA Table Injury caused by DTaP, petitioner must show the following four elements: i) that petitioner had "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; ii) that her pain occurred within 48 hours of the DTaP vaccination; iii) that her pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and iv) that no other condition or abnormality is present that would explain the patient's symptoms. *See* 42 C.F.R. § 100.3(c)(10).

biceps aponeurosis, both of which are just above the elbow. Additionally, petitioner had an MRI of her elbow which confirmed her tendonitis at the level of the elbow. Petitioner was diagnosed with epicondylitis. Because petitioner's medical records do not show her to have suffered a shoulder injury consistent with a SIRVA, she is not entitled to any presumption of causation and must satisfy the burden of proof explained below.[4]

IV. Petitioner Has Not Met Her Burden of Proof

To receive compensation in the Vaccine Program in the absence of a designated Table Injury, petitioner must prove that she suffered an injury that was actually caused by a covered vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(A) and 11(c)(1). Petitioner bears the burden of proving her case by a preponderance of the evidence (i.e. that her allegations are more likely than not). 42 U.S.C. § 300aa-13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must show by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Significant to this case, the Vaccine Act itself forbids a special master from ruling in petitioner's favor based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1).

In this case, petitioner's medical records do not include any medical opinion sufficient to support vaccine causation (or significant aggravation) under the above-described burden of proof. Petitioner wrote in her response to my Order to Show Cause that "[a]ccording to my rheumatologist, Dr. Dhar, 'Vaccines are designed to create an immune response.' So therefore, if someone has a latent issue, a vaccine containing an often irritating agent such as Tetanus Toxoid, can awaken latent issues that otherwise, would remain intact." (ECF No. 46, p. 2.) Significantly, however, this opinion is not reflected anywhere in Dr. Dhar's treatment notes. Nor has petitioner submitted anything in Dr. Dhar's own writing to suggest he has so opined. Although some of petitioner's treating physicians noted her injury as potentially secondary to vaccine-caused inflammation, they did not describe a medical theory explaining how this could be possible. Nor is it readily apparent how this would occur. Also notable, petitioner's orthopedist, Dr. Alcid, described petitioner's injury only as "possibly" due to her vaccination. (Ex. 3, p. 36.) This is insufficient to meet petitioner's burden of proof. The Federal Circuit has stressed that "[w]e have consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Secretary of Health & Human Services*, 941 F.3d 1351, 1360 (Fed. Cir. 2019).

[4] In her response to the Order to Show Cause, petitioner notes that her injury manifested within 2-28 days of her vaccination, which she says is consistent with the Vaccine Injury Table. (ECF No. 46, p. 1.) This timeframe is listed on the Vaccine Injury Table relative to the condition of brachial neuritis. 42 C.F.R. § 100.3(a). There is no evidence in this case that petitioner suffered brachial neuritis.

I understand that petitioner has a strongly held personal view that her injury was caused by her vaccination based on the onset of her symptoms being temporally proximate to her vaccination. I also understand that this injury had a significant impact on petitioner's life regardless of its cause. Critically, however, as a legal matter, a temporal association between vaccination and injury is not enough standing alone to demonstrate causation-in-fact under the standards of this program. *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to Prong Two when respondent conceded that petitioner met Prong Three). Only a small subset of specific injuries designated on the Vaccine Injury Table get any kind of causal presumption based on temporal association. 42 U.S.C. §300aa-13(a)(1)(A) and 11(c)(1). As noted above, petitioner has not alleged any of those injuries (nor do her medical records reflect such an injury).

My examination of the record does not disclose any evidence that petitioner suffered a "Table Injury." And, as explained above, petitioner's medical records do not support her cause-in-fact claim by preponderant evidence and do not include a medical opinion by any treating physician adequate to support her claim. Petitioner has not filed any expert report to support her claim. Accordingly, she has not met her burden of proof.

V. Petitioner's Request for More Time is Denied

Pursuant to Vaccine Rule 8(a), the special master "will determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties." Vaccine Rule 8(d) expressly authorizes the special master to decide a case based on the written record without holding an evidentiary hearing. Moreover, Vaccine Rule 21(b)(1) provides that "[t]he special master or the court may dismiss a petition or any claim therein for failure of the petitioner to prosecute or comply with these rules or any order of the special master or the court."

To date I have granted multiple prior motions for extension of time, providing petitioner well over a full year within which to secure an expert opinion. On November 3, 2020, I advised that this case would be dismissed if an expert report was not filed by February 1, 2021. (ECF No. 45.) In response, petitioner suggests that her inability to secure an expert opinion is primarily the result of the current Covid pandemic and that more time is therefore warranted. (ECF No. 46.) I have considered petitioner's request for additional time. I am very sympathetic regarding the difficulties the pandemic has caused and I realize that pandemic restrictions may lead to some delay. However, petitioner's request is unavailing for several reasons.

First, petitioner was first put on notice regarding respondent's defense of this case in June of 2019 and was first ordered to file an expert report in November of 2019. Pandemic-related lockdowns did not begin until March of 2020. In my experience, the

amount of time petitioner had to secure an expert opinion prior to any significant pandemic-related disruptions would have been reasonable in itself. Second, petitioner has not been alone in her efforts. She is represented by counsel who is familiar with the requirements of this program and who has access to litigation resources that aid in the retention of experts. However, petitioner's counsel confirmed in June of 2020, more than six months ago, that no expert could be retained. Third, petitioner indicates in her response to the Order to Show Cause that she is cold-calling rheumatologists; however, she has indicated in prior filings that she anticipated being able to secure an opinion from one of her own treating physicians. This should not require cold-calling or an in-person visit and was part of the reason that petitioner's time has been extended for as long as it has. However, petitioner has been unable to secure a supporting opinion even from these physicians with whom she is already in contact and whom she represents hold opinions consistent with her claim. Finally, despite the difficulties of the Covid pandemic, experience has shown that litigation has not fully halted. In my experience, the overall amount of time petitioner has been allowed to secure an expert opinion has been generous even when accounting for pandemic-related complications and delays. All of these factors lead me to conclude that an additional extension of time is not warranted in this case.

VI. Conclusion

Petitioner has been unable to comply with the order to file an expert report despite the assistance of experienced counsel who has investigated that possibility and confirmed that potential experts have declined to support this case. Moreover, petitioner has had a full and fair opportunity to present her claim and has been unable to meet her burden of proof. Accordingly, this case is now **DISMISSED**. The clerk of the court is directed to enter judgment in accordance with this decision.[5]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[5] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.